IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Michael J. Rutter	:	Attorney Docket No.: CHM-010
Serial No.: 10/737,128	:	Art Unit: 3743
Filed: December 15, 2003	:	Examiner: Nihir B. Patel
Title: TRACHEOTOMY ENDOTRACHEAL TUBE	:	

DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents
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Comes now MICHAEL J. RUTTER, MD, who is competent to testify as to the matters stated herein, and who makes the following declaration based on his personal knowledge, medical training and belief:

1. I am a Pediatric Otolaryngologist and the Director of Clinical Research at Cincinnati Children's Hospital Medical Center in Cincinnati, Ohio.
2. I am certified by the American Board of Otolaryngology and the Ohio State Medical Board.
3. I am the inventor of claims 1 through 26 of the above-identified patent application.
4. I have conceived and reduced to practice the tracheotomy endotracheal tube as described and claimed in my application.
5. During the development of my invention, I used anatomical measurements typically seen by me through my experiences of many years of clinical medical practice to create the tracheotomy tube claimed in the current application.

6. Specifically, I used the following anatomical reference points to create the claimed tube: the distance from stoma site in the trachea to the carina (covered by the distal section of the tube); the distance from the inner trachea to the chest wall (covered by the intermediate section of the tube); and the distance from the stoma site at the chest wall to the oxygen source (covered by the proximal section of the tube).

7. These ratios are not a matter of design choice, but are necessary for my tube to function as intended.

8. During the development of my invention, I found that typically a 2 year-old patient requiring a tracheostomy has a distance of between about 6 cm to about 8 cm from the stoma site in the trachea to the carina (the carina being the bifurcation point of the trachea into the bronchial tree); a distance of between about 4 cm to about 6 cm from the inner trachea to the chest wall; and a distance of between about 20 cm to about 24 cm from the chest wall to the oxygen source (which would be positioned away from the patient during surgery).

9. Similarly, during the development of my invention, I found that typically in an 8 year-old patient there is a distance of between about 8 cm to about 10 cm from the stoma site in the trachea to the carina; a distance of between about 5 cm to about 8 cm from the inner trachea to the chest wall; and a distance of between about 24 cm to about 28 cm from the chest wall to the oxygen source.

10. During the development of my invention, I found that in a typical adult patient (male or female), there is a distance of between about 10 cm to about 12 cm from the stoma site in the trachea to the carina; a distance of between about 6 cm to about 10 cm from the inner trachea to the chest wall; and a distance of between about 30 cm to about 35 cm from the chest wall to the oxygen source.

11. All of the above-stated distances are important to the proper use and function of my tube.

12. With all of the above-stated distances there is a common thread wherein the ratio of the length of the distal section to the length of the intermediate section is from about 1.0 to about 2.0, and the ratio of the length of the proximal section to the length of the distal section is from about 2.0 to about 4.0.

13. Further, these claimed ratios can be narrowed such that the ratio of the length of the distal section to the length of the intermediate section is from about 1.2 to about 1.8, and the ratio of the length of the proximal section to the length of the distal section is from about 2.5 to about 3.5.

14. If the claimed ratios are not used then there is an increased likelihood for untoward events to occur.

15. Regarding the proximal section, it is important during surgery for the anesthesiologist to have access to the patient's airway. If the surgeon is operating in the mouth or upper airway, then the anesthesiologist is relegated to place the anesthesia machine in an area of the operating room that is located an uncomfortable distance away from the patient's upper airway. Thus, if the proximal section of the tracheostomy tube is elongated, as is claimed in my application, then the anesthesiologist can easily access the connection of the tube to the anesthesia machine, which carries oxygen to the patient. Therefore the proximal section of tubing is necessarily elongated in order to allow the anesthesiologist access to the tube and to keep the tube away from the body cavity of the patient during use.

16. The undersigned hereby declares that all statements made herein are based upon my knowledge and are true, and that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine, imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issued therefrom.

Further Declarant sayeth naught.

Dated: 7/6/05

Michael J. Rutter, MD